UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHARLES SEIFE, Plaintiff, -v- FOOD AND DRUG ADMINISTRATION, et al., Defendants.	:	17-CV-3960 (JMF) MEMORANDUM OPINION AND ORDER

JESSE M. FURMAN, United States District Judge:

This case arises out of a request, pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, for information from the Food and Drug Administration ("FDA") regarding the testing and approval process for Exondys 51, a drug created by Sarepta Therapeutics, Inc. ("Sarepta") for the treatment of Duchenne Muscular Dystrophy ("DMD"), a rare neuromuscular disease. *See* Docket No. 1. Pursuant to a stipulation between the parties, the FDA produced over 35,000 pages of documents to Plaintiff Charles Seife, some of which were redacted pursuant to FOIA Exemption 4 ("Exemption 4") for documents containing "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4); *see* Docket No. 91 ("Seife 56.1 Resp.") ¶¶ 51, 52; Docket No. 39. Now pending are cross-motions for summary judgment — filed by Seife, the FDA, and Sarepta (which was granted leave to intervene) — regarding the propriety of those redactions. *See* Docket Nos. 69, 74, 85; *see also* Docket Nos. 44, 47. The Court is reserving judgment on those motions pending the Supreme Court's decision in *Food Marketing Institute v. Argus Leader*

Media, which concerns the meaning of "confidential" in FOIA Exemption 4. *See* Pet. for Cert. at i, No. 18-481 (U.S. Oct. 11, 2018), *cert. granted*, 139 S. Ct. 915 (2019).[1]

There are, however, two matters that the Court can — and, to take advantage of the delay in waiting for the Supreme Court, should — resolve now. First, Seife filed a motion to strike two declarations of Ian Estepan, the Chief of Staff and Head of Corporate Affairs at Sarepta. Docket No. 94 ("Pl. Mem."), at 1; Docket No. 112 ("Pl. Reply"), at 15-16, 19; *see* Docket No. 72 ("Estepan Decl.") ¶ 1; Docket No. 105 ("2d Estepan Decl.").[2] Whether or not a motion to strike is filed, "[o]n a motion for summary judgment, a district court may rely only on material that would be admissible at trial." *Rubens v. Mason*, 387 F.3d 183, 189 (2d Cir. 2004). That is, a district court may rely on an affidavit or declaration when deciding a motion for summary judgment only if it is "made on personal knowledge, set[s] out facts that would be admissible in evidence, and show[s] that the affiant or declarant is competent to testify on the matters stated." Fed. R. Civ. P. 56(c)(4); *see also Presbyterian Church of Sudan v. Talisman Energy, Inc.*, 582 F.3d 244, 264 (2d Cir. 2009); Fed. R. Evid. 602. In deciding an evidentiary question, a court may "strike portions of an affidavit that are not based upon the affiant's personal knowledge,

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[1] Strictly speaking, *Food Marketing Institute* involves a FOIA request governed by pre-2016 FOIA, while this case involves a request governed by the statute as amended in 2016. *See* 5 U.S.C. § 552(a)(8)(A)(i); FOIA Improvement Act of 2016, Pub. L. No. 114-185, 130 Stat. 538; *see also* Docket No. 128. Nevertheless, the Court believes that it is prudent to await the Supreme Court's possible guidance in light of the similarity of the FOIA statute pre- and post-amendment. *See, e.g.*, *Cause of Action Inst. v. U.S. Dep't of Justice*, 330 F. Supp. 3d 336, 355 (D.D.C. 2018) (noting the Department of Justice's argument that the 2016 Act "does not alter the scope of the information covered by the exemption").

[2] The motion also seeks to strike a paragraph from the declaration of Nancy Sager, a director at the FDA, on the ground that it is derived from one of the Estepan declarations. Pl. Mem. 1; *see* Docket No. 77 ("Sager Decl.") ¶ 37 ("The information redacted . . . is exempt from disclosure under FOIA Exemption 4 because, *as Sarepta claims in the Declaration of Ian Estepan* . . . , the information is confidential commercial information that would cause competitive harm to Sarepta if disclosed." (emphasis added)).

contain inadmissible hearsay or make generalized and conclusory statements." *Hollander v. Am. Cyanamid Co.*, 172 F.3d 192, 198 (2d Cir. 1999), *abrogated on other grounds by Schnabel v. Abramson*, 232 F.3d 83 (2d Cir. 2000). Alternatively, it may, without granting a motion to strike, simply "decline[] to consider evidence" from the inadmissible declarations. *Fabrication Enters., Inc. v. Hygenic Corp.*, 64 F.3d 53, 59 n.5 (2d Cir. 1995).

Applying these standards, Seife's motion is denied to the extent that it seeks to strike the Esteban declarations in their entirety. The declarations establish that Estepan spent fifteen years investing in healthcare, through which he learned "what types of information about drug development are of interest to investors and commercially valuable." 2d Estepan Decl. ¶ 7. Estepan "regularly communicate[s] with investors . . . about investments in Sarepta vis-à-vis its competitors" and "closely track[s] the evolving competitive landscape in DMD." *Id.* ¶¶ 23, 24. He also regularly reviews "medical literature regarding DMD," "reports of nonclinical and clinical trials," and "submissions to the FDA and other regulators"; and he frequently "visit[s]" and "consult[s] with" Sarepta's scientific, medical, and technical personnel. *Id.* ¶¶ 13, 14, 16, 17, 19. All of that qualifies Estepan to testify to the competitive harms that the disclosures at issue could cause, even if he does not understand the precise scientific value of the disclosures. *See, e.g., NRDC v. U.S. Dep't of Interior*, 36 F. Supp. 3d 384, 402 n.10 (S.D.N.Y. 2014) (holding that a declaration is based on personal knowledge even though "the declarants did not know, but c[ould] only infer," the relevant conclusion). It also qualifies Estepan to testify to actions he supervises, rather than directly conducts. *See, e.g.*, *Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 814 (2d Cir. 1994) (holding that affidavits from a supervising employee are sufficient.). Many of Seife's arguments to the contrary go to credibility rather than admissibility. Thus, Seife's motion to strike is DENIED to the extent it seeks to strike the Esteban declarations in their entirety. The

Court will, as necessary, resolve Seife's challenges to the particular paragraphs of the declarations when deciding the parties' motions for summary judgment.

Second, whatever the Supreme Court may decide in *Food Marketing Institute*, the Court is persuaded that Seife is entitled to at least some relief on the ground that the FDA (at Sarepta's request) improperly redacted information that is already public. Exemption 4 does not apply to confidential commercial information "if identical information is otherwise in the public domain" and "freely available" there. *Inner City Press/Comty. on the Move v. Bd. of Governors of the Fed. Reserve Sys.*, 463 F.3d 239, 244 (2d Cir. 2006) (internal quotation marks omitted).[3] In this case, Seife has established — through a sample of the documents at issue — that the FDA's redactions are overbroad. Specifically, in response to Seife's line-by-line challenges to the sample redactions, Sarepta conceded that over half the sample pages — 54% by Seife's calculation — included improper redactions of public information; 12% of the pages with challenged redactions have been unredacted altogether. *See* Docket No. 114 ("Seife Reply Decl.") ¶¶ 2-5. For example, in response to the twenty-two objections listed in Exhibit B to the Kenney Declaration submitted in support of Seife's motions, Sarepta admitted that fourteen included incorrect redactions. *See* Docket No. 90 ("Kenney Decl."), Ex. B; Docket No. 104 ("Sherwood Decl."), ¶¶ 22-26, 28, 31, 33-35, 38-40, 42. In response to Seife's nine pairs of page-by-page comparisons of redactions and public information, Sarepta admitted that three included incorrect redactions. *See* Kenney Decl. Ex. C; Sherwood Decl. ¶¶ 12-20. Moreover, the mistakes were not isolated to one category of information, but rather extended to information

[3] The Court is unpersuaded by Seife's contention that the exception to Exemption 4 for publicly available information applies to information that is "largely public" or can be "easily discerned" based on public information. *See* Pl. Reply 9. The publicly available information must be "identical." *Inner City Press*, 463 F.3d at 244 (internal quotations mark omitted).

in all four disputed categories of redactions (namely, study procedures, test results, endpoints, and adverse events). *See* Kenney Decl. Ex. C.

In light of that showing, the Court concludes that Sarepta and the FDA should be required to re-review and, as necessary re-redact, the documents that are in dispute. Sarepta's conclusory assertions notwithstanding, *see* Docket No. 101, at 28-29 (arguing that any problem with the samples does not "render the entire review process unreliable" because its redaction process was reliable), there is "no indication" that the samples discussed above "are not fairly representative of the documents and proposed redactions." *Associated Press v. U.S. Dep't of Def.*, 498 F. Supp. 2d 707, 709 (S.D.N.Y. 2007). To the contrary, the record indicates that the FDA and Sarepta used the same process to redact the samples that they used for all the redactions in this case. *See* Seife Reply Decl. ¶ 6; Sherwood Decl. ¶ 4; Sager Decl. ¶¶ 28-29, 31-32. It would be foolhardy to conclude, therefore, that the problems found in the sample submitted to the Court are not likely to be found in the other documents. It follows that Sarepta and the FDA should, while the Court awaits a Supreme Court decision in *Food Marketing Institute*, be required to revisit their redactions to the rest of the documents. *See, e.g.*, *Halpern v. FBI*, 181 F.3d 279, 298 (2d Cir. 1999) (endorsing a "representative sample" approach to evaluation of FOIA disputes); *cf. Associated Press*, 498 F. Supp. 2d at 709 (approving of proposed redactions in light of a review of a "representative sample" of the documents at issue).

Accordingly, Sarepta is ORDERED to re-review its redactions to the full FOIA production in accordance with this Memorandum Opinion and Order; to unredact any publicly available information; and to provide the revised redactions to the FDA. The FDA, in turn, is ORDERED to review the revised redactions to ensure they comply with this Memorandum Opinion and Order and to then provide the revised documents to Seife. Unless and until the

Court orders otherwise, Sarepta and the FDA shall complete those tasks no later than **June 26, 2019**. Further, the parties shall promptly meet and confer in an effort to agree upon a proposed order establishing protocols (if appropriate) and rolling deadlines for the foregoing review. The parties shall submit any such proposed order (or competing orders) no later than **April 3, 2019**.

Finally, **within one week of** (1) the June 26, 2019 deadline for the production of documents re-reviewed in accordance with this Memorandum Opinion and Order and (2) the Supreme Court's decision in *Food Marketing Institute*, whichever is later, the parties shall submit a joint letter addressing whether the Court should (a) require or allow the parties to submit supplemental briefs in connection with the summary judgment motions; (b) deny the current motions without prejudice to filing new motions; or (c) decide the current motions based on the existing submissions. In the meantime, given the wait for the Supreme Court, the current motions will be administratively terminated.

The Clerk of Court is directed to terminate Docket Nos. 69, 74, 85, and 93.

SO ORDERED.

Dated: March 27, 2019
New York, New York

JESSE M. FURMAN
United States District Judge